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Submitted by:	Smith & Nephew, Inc. Advanced Surgical Devices Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	October 17, 2013
Contact Person and Address:	Megan Fessenden Regulatory Affairs Specialist T 901-399-1104 F 901-721-2583
Name of Device:	Smith & Nephew, Inc. Global Femoral Head Trials
Common Name:	Orthopaedic Surgical Instrumentation
Device Classification Name and Reference:	21 CFR 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR 888.3358 Hip joint metal/polymer metal semi-constrained porous-coated uncemented prosthesis 21 CFR 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis 21 CFR 888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	LZO, KWY, LWJ, LPH, JDI, MEH, MBL

OCT 2 2 2013

Device Description

Per U.S Food and Drug Administration (FDA) regulation, device-specific instruments are accessory devices and take on the classification of the device(s) with which they are used. Instruments that are designed to assist in the implantation of Class II Smith & Nephew Hip Systems are classified as Class II devices and are subject to premarket notifications and regulations.

The subjects of this 510(k) are the Smith & Nephew Global Femoral Head Trials. The femoral head trials are instruments used to assist in the implantation of cleared Smith & Nephew hip systems.

Intended Use

Smith & Nephew Global Femoral Head Trials are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Hip Systems in their cleared Indications for Use as provided below.

Smith & Nephew Uncemented Femoral Stems

Smith & Nephew Uncemented Femoral Stem Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Uncemented Hip Systems and their cleared Indications for Use.

Uncemented Femoral Stems are indicated for uncemented use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Smith & Nephew Cemented Femoral Stems

Smith & Nephew Cemented Femoral Stem Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Cemented Hip Systems and their cleared Indications for Use.

Cemented Femoral Stems are indicated for cemented use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Smith & Nephew Inc. PLUS Femoral Stems

Smith & Nephew PLUS Femoral Stem Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew PLUS Hip Systems and their cleared Indications for Use.

Smith & Nephew Inc PLUS Femoral Stems are indicated for:

- The SL-PLUS Stem Primary is intended for treating patients who are candidates for total hip arthroplasty because the natural femoral head and neck has been subject to disease or trauma. The SL-PLUS Stem is intended for advanced hip joint wear due to

degenerative, posttraumatic or rheumatoid arthritis; fracture or avascular necrosis of the femoral head.

- The SLR-PLUS STEM, a revision component, is also available to replace previously failed femoral him arthroplasties. Both components can be used with or without cement. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.
- The SL-PLUS Lateralized Stem is intended for varus femur forms and trumpet shape of the proximal femur (champagne flute). These stems are for uncemented use only. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.
- The SL-PLUS MIA Stem is indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.
- The POLARSTEM Standard and Lateral Femoral Stems are indicated for: advanced degeneration of the hip joint as a result of degenerative, post-traumatic or rheumatoid arthritis, fracture or avascular necrosis of the femoral head, failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement, all forms of osteoarthritis, patients with hips at risk of dislocation, and femoral neck fracture or proximal fracture to hip joint.

Technological Characteristics

The subject devices are similar to existing femoral head trials currently being used by surgeons when implanting femoral hip systems. The trials are manufactured from polyphenylsulfone (PPSU) with up to 10% of the radiopacifier barium sulfate. In addition, colorants are blended into the PPSU resin to allow for differentiation between the various sizes. The same materials are used in the manufacturing of existing hip system trials.

Substantial Equivalence Information

When compared to the previously cleared device-specific instruments listed in Table 2, the proposed instruments utilize the same raw materials, manufacturing processes, and sterilization methods (where applicable). It should also be noted that the nature of body contact is the same as found with the predicate devices that have been identified in this premarket notification.

Table 2: Substantially Equivalent Predicates to the Global Femoral Head Trials

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew	Radiopaque Trial Necks	K113039	10/5/2012

Conclusion

This Traditional 510(k) Premarket Notification is being submitted to request clearance for the Global Femoral Head Trials. Based upon the technological and material similarities, the devices are substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 22, 2013

Smith & Nephew, Incorporated
Ms. Megan Fessenden
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K132435
Trade/Device Name: Global Femoral Head Trials for use with Smith & Nephew, Inc. Uncemented, Cemented and PLUS Femoral Stems
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, KWY, LWJ, LPH, JDI, MEH, MBL
Dated: August 26, 2013
Received: August 28, 2013

Dear Ms. Fessenden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Global Femoral Head Trials
Indications for Use

510(k) Number (if known): K132435 page 1 of 4

Device Name: **Global Femoral Head Trials** for use with Smith & Nephew Inc. Uncemented Femoral Stems

Indications for Use:

Smith & Nephew Uncemented Femoral Stem Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Uncemented Hip Systems and their cleared Indications for Use.

Uncemented Femoral Stems are indicated for uncemented use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Prescription Use	X	AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices

Global Femoral Head Trials
Indications for Use

510(k) Number (if known): K132435 page 2 of 4

Device Name: **Global Femoral Head Trials** for use with Smith & Nephew, Inc. Cemented Femoral Stems

Indications for Use:

Smith & Nephew Cemented Femoral Stem Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Cemented Hip Systems and their cleared Indications for Use.

Cemented Femoral Stems are indicated for cemented use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Prescription Use	X	AND/OR	Over-The-Counter Use	
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices

Global Femoral Head Trials
Indications for Use

510(k) Number (if known): K132435 page 3 of 4

Device Name: **Global Femoral Head Trials** for use with Smith & Nephew Inc PLUS Femoral Stems

Indications for Use:

Smith & Nephew PLUS Femoral Stem Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew PLUS Hip Systems and their cleared Indications for Use.

Smith & Nephew Inc PLUS Femoral Stems are indicated for:

- The SL-PLUS Stem Primary is intended for treating patients who are candidates for total hip arthroplasty because the natural femoral head and neck has been subject to disease or trauma. The SL-PLUS Stem is intended for advanced hip joint wear due to degenerative, posttraumatic or rheumatoid arthritis; fracture or avascular necrosis of the femoral head.
- The SLR-PLUS STEM, a revision component, is also available to replace previously failed femoral him arthroplasties. Both components can be used with or without cement. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.
- The SL-PLUS Lateralized Stem is intended for varus femur forms and trumpet shape of the proximal femur (champagne flute). These stems are for uncemented use only. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

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Global Femoral Head Trials
Indications for Use

510(k) Number (if known): K132435 page 4 of 4

Device Name: **Global Femoral Head Trials** for use with Smith & Nephew Inc PLUS Femoral Stems

Indications for Use (continued):

- The SL-PLUS MIA Stem is indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.
- The POLARSTEM Standard and Lateral Femoral Stems are indicated for: advanced degeneration of the hip joint as a result of degenerative, post-traumatic or rheumatoid arthritis, fracture or avascular necrosis of the femoral head, failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement, all forms of osteoarthritis, patients with hips at risk of dislocation, and femoral neck fracture or proximal fracture to hip joint.

Prescription Use	X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)			(21 CFR 807 Subpart C)

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